REMARKS / ARGUMENTS

I. Rejection of Claims 8-11, 35 and 39-42 under 35 U.S.C. §112 first paragraph

The Examiner rejects claims 8-11, 35 and 39-42 states that the claims fail to comply with the enablement requirement. Applicants disagree. The Examples demonstrate that the invention as claimed is enabled.

The Examiner states that the specification fails to enable the use of immunogenic / pharmaceutical compositions / vaccines comprising solely the isolated nucleic acid encoding SEQ ID NO:2, 4 or 6, or immunogenic / pharmaceutical compositions / vaccines comprising the isolated nucleic acid encoding SEQ ID NO:2, 4 or 6 linked to a promoter. Applicants point out that there are three independent claims (claims 8, 10 and 26), all of which recite that "*the nucleic acid molecule is operatively linked to a promoter for expression of the polypeptide in a mammalian cell*".

The Examiner is directed to Examples 1-9. In these Examples, Applicants show that the recited nucleic acid molecules, linked to a promoter for expressing the polypeptide in a mammalian cell, induced an immune response. This was achieved without requiring a recombinant host cell. Moreover, the nucleic acid induced not only an immune response, but a protective immune response; i.e. the DNA worked as a vaccine.

Examples 1 and 2 on pages 51-52 show construction of plasmid vector pCACPNM555a (Figure 4) encoding the full length 76kDa protein (SEQ ID NO:2) under control of the CMV promoter. Example 3 describes immunizing mice with the pCACPNM555a plasmid, and demonstrates that the mice are subsequently protected when they are challenged with *C. pneumoniae* (Table 1 and Figure 7).

Examples 4 and 5 on pages 56-57 show construction of plasmid vector pCAI555 (Figure 5) encoding a 5' truncation of the 76kDa protein (SEQ ID NO:4) under control of the CMV promoter. Example 6 describes immunizing mice with the

pCAI555 plasmid, and demonstrates that the mice are subsequently protected when they are challenged with *C. pneumoniae* (Table 2 and Figure 8).

Examples 7 and 8 on pages 60-61 show construction of plasmid vector pCAD76kDa (Figure 6) encoding a fusion comprising a 3' truncation of the 76kDa protein (SEQ ID NO:6) under control of the CMV promoter. Example 9 describes immunizing mice with the pCAD76kDa plasmid, and demonstrates that the mice are subsequently protected when they are challenged with *C. pneumoniae* (Table 3 and Figure 9).

The Examiner is therefore incorrect in stating that "The specification fails to provide adequate guidance regarding how one would prepare a nucleic acid which when introduced into a host would induce an immune response against the protein encoded by said nucleic acid." In fact, the specification does provide such a teaching. Rejection of claims 8-11, 35 and 39-42 under 35 U.S.C. §112 first paragraph should be withdrawn.

II. Rejection of Claim 46 under 35 U.S.C. §112 second paragraph

The Examiner states that claim 46 is indefinite because of the recitation "optionally". The term "optionally" has been removed from the claim.

III. Rejection of Claims 8-11, 35 and 39-42 under 35 U.S.C. § 103(a) – Nat. Genet. 62(3):880-886 (Kalman') and US patent 6,449,294 B1 ('Griffais')

The Examiner's citation of Kalman et al Nat. Genet. April 1999. 62(3):880-886 is still not understood. Applicants cannot locate such a reference and assume the intended citation is Kalman et al. Nature Genetics. April 1999. 21:385-389 (reference A35 on IDS filed January 14, 2004).

The Examiner rejects claims 8-11 35 and 39-42 as being obvious in view of Kalman in combination with Griffais. Applicants disagree.

Griffais describes the sequencing of the *Chlamydia pneumoniae* genome and identifies 1296 putative reading frames (see Table 1 of Griffais). Griffais states that any of the 1296 putative reading frames they disclosed might be expressed and might work as a vaccine. As noted by the Examiner in the Office Action issued on March 30, 2004, the sequences disclosed by Griffais are different from those recited in the claims of the present application.

Griffais' relevant date under 35 U.S.C. 102(e) is November 4, 1998.

Attached is a declaration by inventor Andrew Murdin, filed pursuant to 37 C.F.R. 1.131. The declaration states that Dr. Murdin is inventor in 13 U.S. applications filed before November 4, 1998 which describe 13 antigens representative of polypeptides encoded by the *C. pneumoniae* genome. These 13 applications describe expressing the 13 antigens in host cells, and using these antigens as vaccines to immunize a host against Chlamydia.

Dr. Murdin's declaration shows that before November 4, 1998, the inventors had filed for patent applications in the U.S. for using the genes and polypeptides encoded by *C. pneumoniae* to make vaccines against Chlamydia. Griffais disclosed no more than this. The inventors possessed the subject matter described by Griffais before November 4, 1998. Therefore, Griffais is not prior art under 35 U.S.C. 103(a).

The Examiner's basis for rejecting the claims under 35 U.S.C. § 103(a) is the combination of Griffais and Kalman. Griffais is not prior art. Accordingly, the rejection under 35 U.S.C. § 103(a) in view of Griffais and Kalman should be withdrawn.

IV. Concluding Remarks

In view of the above amendments and remarks, reconsideration and favorable action on all pending claims are respectfully requested. If any questions or issues remain, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

If a fee is required for an extension of time which is not accounted for, such an extension is requested and the U.S.P.T.O. is authorized to withdraw from our Deposit Account Number 19-0741 any fee required.

Respectfully submitted,

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